K093562

510(K) PREMARKET NOTIFICATION SUMMARY

Name/Address of Submitter: Southern Implants, Inc.
5 Holland, Bldg. 209
Irvine, CA 92618

OCT 14 2010

Establishment Registration Number: 3003845138

Contact Person: Michael A. Kehoe
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Date Summary Prepared: October 20, 2009

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640

Device Regulatory Status: Class II Special Controls

Trade Name: Zygomatic Implant

Purpose: The purpose of this 510(k) is to include additional implants and accessories in the Southern Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions.

Performance Standards: FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in Southern's Zygomatic Implant System meet applicable voluntary standards. Southern Implant's screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV Titanium.

Predicate Devices: K970499 Branemark System Zygomatic Implant; K070182 Nobel Biocare Zygoma Implant

Device Description and Intended Use: The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with fully or partially edentulous maxillae.

Sterilization Methods Used: Sterilization of these implants will be achieved using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10^{-6}. Validation of sterilization will be done as specified by the Association for the Advancement of Medical Instrumentation (AAMI). Standards utilized include:

ISO 11137	Sterilization of Health Care Products – Requirements for validation and routine control – Radiation sterilization
ISO 11137-2	Sterilization of Medical Devices – Microbial Methods – Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13409	Sterilization of Health Care Products – Radiation Sterilization – substantiation of 25kGy as a sterilization dose for small or infrequent production batches.

Packaging Method: Please note that our implants are packaged the same as our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. Implants are placed into plastic tubing (PT6.1) and capped on both ends. The plastic tube is then heat sealed in a blister pack consisting of a transparent film (P.E.T.) and a porous sheet material backing (Tyvek1073B). This blister pack is considered the primary pack (that which provides the microbial barrier) for the implants. The Tyvek is coated with an adhesive. A sterilization indicator sticker is placed on the blister packaging. The blister with its contents are then enclosed in a clear plastic box and sent for sterilization.

Packaging Validation: All Southern Implants packaging is validated following these standards:

ASTM D 4169-08	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88-00	Standard Test Method for Seal strength of Flexible Barrier Materials
ASTM F 1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F 1980 – 07	Standard Guide for Accelerated Aging of Sterile Medical Device Packages
EN 552	Sterilization of medical devise – Validation and routine control of sterilization by irradiation
EN556	Sterilization of medical devices – Requirements for medical devices to be labeled "Sterile"
EN 868-1:1997	Packaging materials and systems for medical devices with are to be sterilized: Part 1 General requirements and test methods
EN 868-5:1999	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods
EN 868-9: 2000	Packaging materials and systems for medical devices which are to be sterilized – Part 9: Uncoated non-woven materials of polyolefines suitable for use as packaging of medical devices which are to be terminally sterilized – Requirements and test methods.
EN 868-10:2000	Packaging materials and systems for medical devices which are to be sterilized – Part 10: Adhesive coated nonwoven material of polyolefines for use in the manufacture of heat sealable pouches, reels and lids – Requirement s and test methods
ISO 11607	Packaging for terminally sterilized medical devices

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the NSI Endosseous Dental Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

Surface Modifications: Please note that this is the same surface modification method currently used with our existing line of dental implants that are cleared NSI hexed and non-hexed Implant Systems noted above as predicate devices. The surface of our implant is blasted using 100 micron alumina (Al_2O_3) particles. Alumina is a highly biocompatible material and hence if any particles remain embedded in the surface, they will not pose a complication. The other measure taken to reduce the potential of embeddiment is to blast with relatively low pressure. If the indentations caused are significantly smaller than the size of the blast media, then particles tend to not adhere to the surface. (Our S_a = 1.43 microns is a fraction of the particle size of 110 microns). Each and every implant is visually inspected under a microscope after surface enhancement as a matter of manufacturing protocol. In addition to visual inspection, a sample implant is sent for SEM testing four times a year for evaluation of the surface as well.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Brief Discussion of Engineering Studies: Fatigue studies were conducted as per FDA Class II Special Controls Guidance Document and ISO standard 14801: 2007(E). Testing revealed a stable screw joint at the highest forces tested. See enclosed study.

Conclusions Drawn: The Southern Zygomatic Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

ENCLOSURE 1

Comparison of Properties and Features of Southern's 4.0 mm 55° angle-corrected implant to Nobel Biocare's Zygomatic 45° implant

	Southern 55°angle corrected tapered implant	Nobel Biocare Zygomatic 45° Implant
Specification for material	ASTM Grade IV titanium	Titanium
Exterior geometry	Threaded	Threaded
Implant width at restorative platform (mm)	4.05	4.0
Implant lengths (mm)	35, 37.5, 40, 42.5, 45, 47.5, 50, 52.5, 55	30, 35, 40, 42.5, 45, 47.5, 50, 52.5
Maximum diameter (mm)	4.05	4.1
Apical end diameter (mm)	3.8	2.8
Hex width x height (mm)	2.7 x 0.7	2.7 x 0.7
Internal screw access width (mm)	2.0	2.0
Angle of screw access opening relative to long axis of implant	55°	45°

Indication for Use: The Zygomatic implant is intended to be implanted in the upper jaw arch to provide support for fixed or removable dental prostheses in patients with fully or partially with fully or partially edentulous maxillae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael A. Kehoe
President and Chief Executive Officer
Southern Implants, Incorporated
5 Holland Building 209
Irvine, California 92618

OCT 14 2010

Re: K093562
Trade/Device Name: Zygomatic Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 23, 2010
Received: September 24, 2010

Dear Mr. Kehoe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

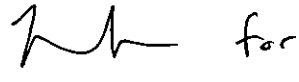
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K093562

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Device Name: Zygomatic Implant System

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Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use _____.
(Per 21 CFR801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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